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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/481,990 | 01/11/2000 | Florian Lesage | 989.6351DIV | 6424 |
| 35811 | 7590 | 11/22/2004 | EXAMINER | |
| IP DEPARTMENT OF PIPER RUDNICK LLP ONE LIBERTY PLACE, SUITE 4900 1650 MARKET ST PHILADELPHIA, PA 19103 | | | LANDSMAN, ROBERT S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/481,990

Applicant(s)

LESAGE ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 11/8/04 has been entered into the record.
- B. Claims 11 and 27 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The objection to the specification has been withdrawn in view of Applicants' replacement of the term "T1-T4" with "M1-M4."
- B. Figure 1 is objected to since there are two Figure 1C's. The Brief Description should be amended accordingly.

3. Double Patenting

- A. The double patenting rejections over co-pending applications 09/436,265; 09/939,483; 09/939,484; 09/892,360 will be held in abeyance until allowable subject matter is identified in the present application.

4. Claim Rejections - 35 USC § 101

- A. Claim 27 remains rejected under 35 USC 101 for the reasons already of record on pages 2-3 of the Office Action mailed 8/5/04. Applicants argue that TWIK derivatives can be used in drug screening. However, the issue remains that any alterations to the TWIK protein of SEQ ID NO:2 would not have utility since it would not be a wild-type protein. This concern remains in large part due to the fact that it appears that all of the functional domains of the TWIK of SEQ ID NO:2 must not be altered according to claim 27. In fact, on page 7 of Applicants' present Response, they state that "the sequence of SEQ ID NO: 2, as shown in Figs. 1B and 2B, are the base sequence from which the claimed functionally equivalent TWIK derivatives can be obtained by varying non-critical amino acid residues." Therefore, it appears that the only amino acids altered in this protein are "non-critical." Therefore, it is not understood how altering non-critical residues can provide any information as to structure-function relationships. It would

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appear, therefore, that no useful information can be gained from altering non-critical residues. Hence, there is no utility for the derivatives of the present invention.

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claim 27 remains rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action mailed 8/5/04 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. Claim 27 remains rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 8/5/04. Applicants' arguments have been considered and are deemed persuasive insofar as they relate to providing the critical amino acids defined as "P1, P2 and M1-M4." In the Interview of 10/4/04 Applicants have clarified that P1, P2 and M1-M4 are, in fact, specifically defined regions based on specific amino acid sequences. This does raise issues as seen below under 35 USC 112, second paragraph. The fact that Applicants are only requiring 50% of the TWIK protein of SEQ ID NO:2 to be retained is sufficient since Applicants have required that the functional domains of SEQ ID NO:2, which would be the pore (P1, P2) and transmembrane regions (M1-M4) be present in any "derivative."

However, the concerns which are now raised are the fact that the region between M1 and P1 does not have any requirements for a defined sequence comprising the corresponding region of SEQ ID NO:2. Therefore, every amino acid in this "loop" could be replaced. The situation is identical for the region between M2 and M3. There is not requirement that these regions of SEQ ID NO:2 be present in these regions in the derivative. Furthermore, Applicants have not demonstrated that a protein comprising only the P1, P2 and M1-M4 (i.e. the regions shown in Figure 1D) would be functional. Applicants have only demonstrated that the full-length of SEQ ID NO:2 is functional.

6. Claim Rejections - 35 USC § 112, first paragraph - written description

A. The rejection of claim 27 under 35 USC 112, first paragraph, has been withdrawn in view of the Interview of 10/4/04 where Applicants have clarified that P1, P2 and M1-M4 are, in fact, specifically defined regions based on specific amino acid sequences. Therefore, both structure and function have been defined in the claim.

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7. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. The rejection of claims 11 and 27 under 35 USC 112, second paragraph, regarding the term “TWIK” has been withdrawn in view of Applicants’ arguments.

B. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have replaced the term “comprises” with “consisting essentially of.” “Consisting essentially of” is a phrase associated with compositions, not SEQ ID NOs. It is suggested that the term “comprising” be used instead.

C. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have listed “P1, P2, M1, M2, M3 and M4.” However, it is not clear as to in what order these regions must occur. (1) The claim should be amended to include, for example, “of the formula M1-P1-M2-M3-P2-M4.” (2) Furthermore, the claim should be amended to either refer to a Figure in which the actual amino acid sequences for P1, P2, M1, M2, M3 and M4 occur, or the sequence of these regions should also be included in the claim. For example, “wherein P1 has the sequence...etc.”

(3) It is not clear, for example, from Figure 1C (**which should read “1D” and the Brief Description of the Figures should be amended accordingly**) where, according to the claim “the amino acid loop between the P1 and the M1 domains” ends and P1 actually begins. The Figure appears to be one continuous P1 loop. (4) Furthermore, it is not clear if the claimed “phosphorylation consensus site between the M2 and M3 domains” comprises the entire region shown in the picture. Therefore, specific amino acid sequence information should be provided.

8. Conclusion

A. No claim is allowable.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647


ROBERT LANDSMAN
PATENT EXAMINER